

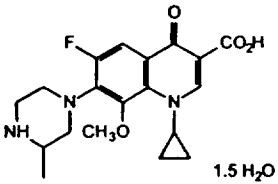
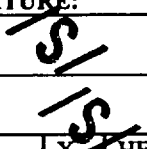
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-061/SE2-007

21-062/SE2-008

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW				1. ORGANIZATION: HFD-590		2. NDA NUMBER: 21-061	
3. NAME AND ADDRESS OF APPLICANT: (City and State) Bristol-Myers Squibb Company 5 Research Parkway Wallingford, CT 06492				4. AF NUMBER:			
				5. SUPPLEMENT(S):			
				NUMBER(S):		DATE(S):	
				SE2-007		21-DEC-2000	
SE2-007-BL		29-AUG-2001					
6. NAME OF DRUG: Tequin				7. NONPROPRIETARY NAME: Gatifloxacin			
8. SUPPLEMENT PROVIDES FOR: A 5-day duration of therapy for Acute Exacerbation of Chronic Bronchitis (AECB)						9. AMENDMENTS/REPORTS:	
10. PHARMACOLOGICAL CATEGORY: Antibacterial (synthetic)			11. HOW DISPENSED: [X] Rx [] OTC		12. RELATED IND/NDA/DMF(S):		
13. DOSAGE FORM(S): Tablets				14. POTENCY(IES): 200 and 400 mg			
15. CHEMICAL NAME AND STRUCTURE: (±)-1-cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-(3-methyl-1-piperazinyl)-4-oxo-3-quinolinecarboxylic acid sesquihydrate <div style="text-align: center;">  </div>						16. MEMORANDA: Environmental Assessment and Finding of No Significant Impact, 08-OCT-2001	
17. COMMENTS: Refer to page 2.							
18. CONCLUSIONS AND RECOMMENDATIONS: This supplement may be APPROVED from the CMC perspective pending resolution of the issues raised by OPDRA. .							
19. REVIEWER: Gene W. Holbert, Ph.D.			SIGNATURE: 			DATE COMPLETED: 12-OCT-2001	
20. CONCURRENCE: Norman R. Schmuff, Ph.D.							
DISTRIBUTION:	X	Original NDA 21-061	X	HFD-590: NSchmuff	X	HFD-590: DWillard	
	X	Division File HFD-590	X	HFD-590: GHolbert	X	HFD-830: CChen	